REMARKS

Claims 1, 3, 10-17 and 19-28 are pending in the application. Claims 1, 3, 17, 19, 21-23, 25, 27 and 28 are presently under examination.

Finality of Previous Office Action Withdrawn

Applicant notes with thanks that the finality of the previous Office Action has been withdrawn.

Previous Claim Objection Withdrawn

Applicant notes with thanks that the previous Claim objections have been withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 1, 3, 17, 19, 21-23, 25, 27 and 28 have been rejected under 35 U.S.C. §103(a) over Weber, WO 2003/026532 (Weber) in view of Weber et al., US 6,743,463 (Weber II) and further in view of Tsipursky et al., US 5,998,528 (Tsipursky). This rejection is respectfully traversed.

For a proper obviousness rejection, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103(a). The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. " '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' " *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn* , 441 F.3d 977, 988 (Fed. Cir. 2006). The prior art reference (or references when combined) must teach or suggest all the claimed features. "When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' … Thus, 'obviousness requires a suggestion of all limitations in a claim.' …" *Ex parte Wada and Murphy*, BPAI Appeal

No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

Weber, Weber II and Tsipursky do not render the currently claimed invention unpatentable under 35 USC 103(a), which invention is directed to an implantable or insertable medical device comprising a release region, said release region comprising (a) a polymeric carrier comprising a hydrophobic first polymer and (b) drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; a hydrophilic first therapeutic agent; and a hydrophilic second polymer, wherein the first therapeutic agent *and* hydrophilic second polymer are structurally associated with the silicate particles in that the first therapeutic agent and hydrophilic second polymer occupy spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.

In this regard, Weber at page 7, line 29 to page 8, line 15 describes the technology therein as including a matrix material as follows (emphasis added):

> . . . a matrix material according to the invention may be any material suitable, or later determined to be suitable, for use in such a medical device. The matrix ***material may be any material that is historically or currently utilized, or contemplated for future use,*** in a corresponding medical device not comprising a nanocomposite component. The matrix material ***may be comprised of organic, inorganic or hybrid organic/inorganic materials.*** Additionally, the matrix material may be a single material or a combination of materials, e.g., ***the matrix material may be a metal alloy, copolymer or polymer blend.***
>
> Exemplary matrix materials include, for example, polymers, such as thermoplastics and thermosets. Examples thermoplastics suitable for use as a matrix material include, for example polyolefins, polyamides, polyesters, polyethers, polyurethanes, polyureas, polyvinyls, ***polyacrylics,*** fluoropolymers, copolymers and block copolymers thereof, and mixtures thereof. Representative examples of thermosets that may be utilized as a matrix material include elastomers [*sic*, elastomers] such as EPDM, epichlorohydrin, nitrile butadiene elastomers, silicones, etc. Conventional thermosets such as expoxies, isocyanates, etc. , can also be used. Biocompatible thermosets may also be used and these include, for example, biodegradable polycaprolactone, poly (dimethylsiloxane) containing polyurethanes and ureas, and polysiloxanes.

The Examiner argues that this portion of WEBER teaches a polymer blend and that this description can be used to meet the hydrophobic first polymer second and hydrophilic second polymer element of the claimed invention. This, however, is merely improper hindsight reconstruction, using the present invention as a roadmap.

For example, out of the myriad materials encompassed by the above, a person of ordinary skill in the art would first have to select an organic material, more particularly a polymer, even more particularly a polymer blend. Furthermore, as components of the polymer blend, that person would have to select a combination of a hydrophobic polymer and a hydrophilic polymer. Such a combination is not described Weber. Moreover, there are good reasons *not* to choose such a combination, not the least of which is the fact that such materials do not ordinarily mix with one another (see, e.g., the classic hydrophobic/hydrophilic combination of oil and water).

Moreover, the Examiner points to the polyacrylics recited at page 8, line 8 of Weber (see above) in support of the Examiner's allegation that Weber teaches a hydrophilic polymer for use in a polymer blend. This, however, is not understood as there are known polyacrylics which are hydrophobic. In this regard, see, e.g., paragraph [0034] of U.S. Patent Pub. No. 2008/0193504: "Suitable polymers are silicone oils and elastomers cross-linked hydrophilic polymers such as naturally occurring polymers, polyurethanes, hydrophilic and ***hydrophobic polyacrylic compounds***."

Moreover, in support of the argument regarding the obviousness of claim 1, the Examiner refers page 9, line 4 of Weber, which in larger context is set forth within the paragraph at page 9, lines 3-21 of Weber (emphasis added):

> Examples of materials suitable for use in the nanoparticles include, among others, ***synthetic or natural smectic phyllosilicates including clays and micas (that may optionally be*** intercalated, ***exfoliated*** and/or otherwise chemically modified) such as montmorillonite (mmt), hectorites, hydrotalcites, vermiculite, and laponite; monomeric silicates such as polyhedral oligomeric silsequioxanes (POSS) including various functionalized POSS and polymerized POSS; carbon and ceramic nano- tubes, nano-wires and nano-fibers, including carbon nanofibers and nanotubes of any geometry prepared by electrospinning a carbonizable material, such as polyacrylonitrile; single and multi-walled fullerene nanotubes, silica nanogels, and alumina nano-fibers, as well as metal and metal oxide powders including aluminum oxide (AlO_3), titanium oxide (TiO_2), tungsten oxide, zirconium oxide, gold (Au), silver (Ag), platinum (Pt) and magnetic or paramagnetic materials such as neodinium iron boron or super paramagnetic ferrite oxide (Fe_3O_4) or super paramagnetic maghemite (Fe_2O_3); organic materials including temperature sensitive polymers, such as polyvinylpyrrolidone and n-isopropylacrylamide copolymers or blends, and poloxamer, biodegradable polymers such as poly (lactic) acid, polysaccharide, polyalkylcyanoacrylate, which biodegradable polymers may also be magnetized; and further including polytetrafluoroethylene, and dendrimers or dendrimer metal complexes.

To arrive at the claimed invention, one of ordinary skill in the art would have to choose smectic phyllosilicates over all the other diverse materials listed, and that person would have to further choose to intercalate the thus-selected phyllosilicates, rather than exfoliate them as taught by Weber.

Weber II does not cure the above-noted deficiencies in Weber. For example, Weber II does not appear to describe, in combination, a hydrophilic polymer and a hydrophobic polymer. In fact, Weber II does not appear to describe polymer blends at all. Nor does Weber II appear to describe intercalated layered silicate particles.

The Examiner notes that Weber and Webber II do not explicitly disclose the placement of the therapeutic agent in the spaces between adjacent layers of the silicate material of each silicate particle to form a depot, but argues that the placement of a hydrophilic therapeutic agent and a hydrophilic polymer in the spaces between the adjacent layers of the silicate material is a property of interaction between the silicate and the hydrophilic therapeutic agent and polymer. In support, the Examiner refers to col. 5, lines 9-19 of Tsipursky, but quotes the text found at col. 4, lines 40-54 of Tsipursky, which in more meaningful context is set forth within the paragraph at col. 4, lines 40-54 of Tsipursky (emphasis added):

> In accordance with an important feature of the present invention, it has been found that the addition of metal cations, preferably during intercalation and/or exfoliation, or the addition of metal cations to a nanocomposite composition of an organic liquid and an intercalate or exfoliate thereof, unexpectedly increases the viscosity of an ***organic liquid-containing nanocomposite composition***. It is preferred that the metal cation has a valence of at least 2, more preferably at least 3, although monovalent salts (preferably not NaOH) also increase the viscosity to a lesser degree. The anion portion of the cation-containing compound, added to provide cations, may be inorganic or organic and the ***cation-containing compound*** is added in solution (with water and/or an organic solvent***) to provide metal cations, as well as anions, in solution***. The addition of the metal cations in solution to the intercalating composition ***results in sufficient intercalation for easy exfoliation using less intercalant***. It is theorized that ***polar moieties from the intercalant molecules***, which complex to the interlayer cations in the interlayer spaces between the platelets of the layered material, also complex with the added cations, and the complexed metal salt-derived cations carry their dissociated anions along with the cations, in the interlayer space, in order to maintain charge neutrality within the interlayer spaces of the layered material. It is theorized that such double intercalant complexing (intercalant with interlayer cations and with cations from the added metal salt compound) occurs on adjacent, opposed platelet surfaces, resulting in repulsion between closely spaced dissociated anions carried by the added cations, resulting in increased basal spacing and more complete exfoliation using less intercalant.

Thus, the system described in Tsipursky includes (a) an organic liquid, (b) intercalant molecules with polar moieties and (c) a cation-containing compound which provides cations as well as anions. This system is totally unrelated to the system proposed by the Examiner on the basis of Weber and Weber II. Moreover, the system is designed for exfoliation, which would destroy the limitation of claim 1 wherein the first therapeutic agent and the hydrophilic second polymer are structurally associated with the silicate particles in that the first therapeutic agent and hydrophilic second polymer occupy spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.

For at least the preceding reasons, claim 1, and claims 3, 17, 19, 21-23, 25, 27 and 28 depending therefrom are patentable over Weber, Weber II and Tsipursky.

Withdrawal of the outstanding rejection under 35 USC §103(a) is thus respectfully requested.

Conclusion

Applicants submit Claims 1, 3, 17, 19, 21-23, 25, 27 and 28 are in condition for allowance. Reconsideration is requested and an early notice of allowance is earnestly solicited. The Examiner is invited to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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